

The development and evaluation of an individualised information package for patients with rectal cancer

Submission date 22/11/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/01/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/11/2015	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Study information

Scientific Title

The development and evaluation of an individualised information package for patients with rectal cancer: a randomised controlled trial

Study objectives

Does a tailored information package for people with rectal cancer affect anxiety, length of consultation and number of follow-up consultations with the Stoma Care Nurse Specialist (SCNS)? Does a tailored information package help to prepare patients for survivorship following a diagnosis of rectal cancer?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Office for Research Ethics Committees in Northern Ireland (ORECNI), approved on 09/07/2008 (ref: 08/NIR01/36)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Other

Health condition(s) or problem(s) studied

Cancer of the rectum

Interventions

The intervention group will receive a series of leaflets from the newly designed information pack depending on their condition, treatment plan and choice of information. To assist people with literacy difficulties and to ensure that the leaflets' content is understood the SCNS will go through a "guided tour" of the information leaflets with each patient in the intervention group.

The intervention group will also receive the usual care that they would receive at any appointment with the Nurse Specialist. The nurse will discuss their condition, treatment options and concerns. The patients will also have an opportunity to ask questions. The control group will receive usual care and will receive the generic colorectal cancer leaflets currently used in usual care. The length of the consultations for both the intervention and control groups will be recorded.

The total duration of the study and follow-up is approximately seven months with data collection at time 1 (at diagnosis) time 2 (just before discharge from hospital after surgery) and time 3 (six months after time 2).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Satisfaction with information, assessed using Patient Satisfaction with Cancer Treatment Education (PS-Ca-TE) at T1, T2 and T3
2. Anxiety will be measured using the Hospital Anxiety and Depression Scale at T1, T2 and T3

3. Health behavioural style, assessed by the Monitor-Blunter style scale at T1 only
4. Preparation for Survivorship will be measured using Reintegration to Normal Living Index at T1, T2 and T3

Length of consultation with the Stoma Care Nurse Specialist and number of follow-up appointments with the Stoma Care Nurse Specialist will be recorded by the Stoma Care Nurse Specialist for the duration of the study for each participant.

Timepoints for data collection:

T1: At diagnosis

T2: Just before discharge from hospital after surgery

T3: Six months after T2

Key secondary outcome(s)

No secondary outcome measures

Completion date

31/08/2010

Eligibility

Key inclusion criteria

1. Both males and females, no age limits
2. Patients with a new diagnosis of rectal cancer

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

Patients at an advanced stage of illness who are under the care of the palliative care team or who are considered to have a prognosis of less than six months.

Date of first enrolment

01/12/2008

Date of final enrolment

31/08/2010

Locations

Countries of recruitment

United Kingdom

Northern Ireland

Study participating centre

Altnagelvin Hospital

Londonderry

United Kingdom

BT47 6SB

Sponsor information

Organisation

Western Health and Social Care Trust (UK)

ROR

<https://ror.org/00sb42p15>

Funder(s)

Funder type

Government

Funder Name

Northern Ireland Health and Social Services Central Services Agency, R&D Office (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No